Online Counseling to Enable Lifestyle-focused Obesity Treatment in Primary Care (OCELOT-PC)

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Abstract

Purpose: First, to use Internet Technology to translate an evidence-based lifestyle intervention into diverse primary care settings, thus facilitating the delivery of preventive counseling. Second, to examine how the use of an electronic tool to identify patients in need of counseling and consequently modulating counseling intensity (i.e., scheduled versus modulated counseling) influences weight loss and cost-effectiveness of an online lifestyle intervention, in comparison with providing online lifestyle goals and resources (OGR) alone.

Scope: 373 patients were recruited from 6 primary care practices in western Pennsylvania from April to December, 2010.

Methods: Obese primary care patients were enrolled into 1 of 3 arms of a randomized controlled trial. Each participant received a lifestyle intervention, consisting of an in-person lifestyle counseling session plus 1 year of access to either comprehensive online intervention with standard coaching (COI-S), comprehensive online intervention with modulated coaching (COI-M) or online goals and resources alone [Online Lifestyle Goals and Resources (OGR)].

Results: All study arms lost weight at 6 months, with the largest effect size seen in the COI-M group [-3.36, 95% confidence interval (CI) -4.70,-2.02], the smallest effect size seen in the OGR arm {-1.91 [95% Confidence Interval (CI): -2.89,-0.94]} and an intermediate point estimate seen for the COI-S arm [-2.44 (CI: -3.39,-1.48)]. Weight loss was sustained at 12 months in each study arm, with point estimates for weight further declining in the COI-M and OGR arms over the second half of the interventions. At each time point, there was no significant difference in weight loss between groups.

Key Words: Obesity, weight loss, information technology, online

Purpose

The purpose of this study is to use Internet Technology to translate an evidence-based lifestyle intervention into diverse primary care settings, thus facilitating the delivery of evidence-based preventive counseling, and to examine how varying the delivery of electronic coaching (i.e., scheduled versus modulated) influences weight loss and cost-effectiveness in an online adaptation of an evidence-based lifestyle intervention, in comparison with provision of online lifestyle goals and resources (OGR) alone.

Scope

In 2009–2010, 35.7% of U.S. adults were obese.[1] In 2003, the US Preventive Services Task Force (USPSTF) recommended that "*clinicians screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults*."[2] Yet the guideline has had minimal impact on physician counseling behavior, with less than half (44%) of physicians providing weight loss counseling in 2005,[3] and multiple studies confirming that counseling for obesity is lacking in primary care settings.[4-7] Barriers such as the time constraints in typical primary care visits and the limitations of physician training have hampered promotion of intensive lifestyle interventions in primary care settings. Further complicating matters is the prohibitive expense involved in delivering the weight loss interventions that have been tested in most efficacy trials.

The Diabetes Prevention Program's (DPP) intensive lifestyle curriculum[8, 9] is one lifestyle counseling program that has been shown to be efficacious for promoting weight loss and has led lead to improvements in diabetes-related and weight-related co-morbidities.[10-12] Efforts to adapt this intervention for effectiveness (versus efficacy) settings have used a number of strategies to reduce intervention costs, such as decreasing the frequency or number of core counseling sessions,[13-15] markedly reducing or eliminating counseling contacts after completion of the core curriculum material,[13-17] employing group-based approaches,[13-20] and using counselors who are not trained health professionals.[14, 16] However, sustained intervention is thought to be important for sustaining behavior change, and access to experts may promote safety, particularly for individuals with weight-related health problems such as diabetes or hypertension. The Internet may facilitate the translation of this preventive counseling curriculum into the clinical setting, while maintaining counseling intensity and providing relevant expert advice and support. A technologic approach also may overcome myriad barriers that have deterred routine delivery of evidence-based lifestyle interventions in the clinical setting. By automating and standardizing much of the counseling process, Internet delivery potentially minimizes staffing costs while increasing patient convenience. Although information technology is considered central to reshaping care and improving healthcare quality in light of the rising burden of chronic disease[21] and it has shown promise for improving clinical care for patients with diabetes,[22] the potential for Internet technology to improve the delivery of preventive medicine advice has not yet been fully realized.

This study enrolled participants from seven primary care practices in western Pennsylvania, which represent a variety of practice settings (e.g., urban, rural, academic, private practice) and patient populations. The practices are all part of the University of Pittsburgh Medical Center Health System, a large, integrated global health enterprise headquartered in Pittsburgh, Pennsylvania.[23] The patient populations of the clinical sites are primarily white or African American, consistent with the region's racial/ethnic distribution, and reflect a range of socioeconomic status.

We included obese patients (BMI $\geq$ 30 kg/m^2) for whom the primary care physician feels that weight loss is appropriate for health. We excluded patients whose PCP felt that moderately intense unsupervised physical activity (the equivalent of 30 minutes of brisk walking) was unsafe. We also excluded those who

did not have the language, sensory or cognitive capacity to learn adequately from English language audio-taped materials; current or planned pregnancy in the next two years; current breast feeding; uncontrolled hypertension; bariatric surgery in the last 2 years, or planned during the next two years; an edematous state that interfered with body weight assessment; participation in a pilot program for this study during the past year; or perceived lack of basic computer or Internet skills

Methods

Overview: This project used a randomized controlled trial design to compare the effectiveness of two online strategies for delivering the DPP lifestyle intervention [comprehensive online intervention with standard coaching (COI-S) or with modulated coaching (COI-M)] to an approach that provides advice and online resources alone [Online Lifestyle Goals and Resources (OGR)]. Both COI strategies automated much of the DPP curriculum's educational counseling, thus reducing the staffing demands compared with the original DPP efficacy trial. All interventions provided physician feedback to promote dialogue between the participant and his/her referring primary care provider (PCP).

Interventions: Participants were randomized to one of three year-long lifestyle intervention groups. Two groups received a comprehensive online intervention (COI) modeled on proven lifestyle intervention from the Diabetes Prevention Program (DPP). The COI program included evidence-based weight and behavior goals, an automated behavioral curriculum, tools to promote lifestyle change, and online counseling support from a lifestyle coach (Table 1). Coaching instructions and tools differed between the two arms. The scheduled COI arm (COI-S) received scheduled coaching (1 note per week during the first 16 weekly lessons or 6 months, then 1 note every other week). The modulated COI arm (COI-M) received coaching only during those weeks in which a need for assistance was apparent, and an electronic tool helped coaches quickly identify those participants who were not meeting program goals (e.g., not logging in, self-monitoring, or completing lessons at the recommended frequency, not meeting dietary or physical activity goals, losing weight too rapidly or experiencing a weight loss plateau).

The third arm [online goals and resources (OGR)] included a single group-session led by a lifestyle coach, in which participants were taught the DPP-based lifestyle goals, educated on the basics of self-monitoring for weight and physical activity, and given a pedometer and a fat/calorie tracking book. They were also given access to the "Resources" page of the COI interventions, which included links to reputable community resources for healthy lifestyles and DPP-based handouts that may be of use in learning to develop a healthier lifestyle.

Table 1. Summary of comprehensive online self-management support tool

Program Goals	Sustained weight loss of ≥7% of body weight (keeping BMI >21 kg/m^2) Gradual increase in moderate physical activity up to 150 minutes per week
Lifestyle teaching:	1 in-person session including education about the DPP's program goals, and discussion of how to pursue these goals safely, then 16 structured, automated online lessons including didactic material and interactive workbook pages. Lessons complemented by tailored coaching advice via electronic messaging 8 structured online maintenance lessons, with interactive workbook paged, based on DPP post-core resource materials. Lessons complemented by tailored coaching advice via electronic messaging
Tools	Pedometer Fat & calorie counter book "Resources page" with links to community resources for healthy lifestyles & DPP-based handouts Online self-monitoring with automated email prompts and weekly graphic reports Online exercises to illustrate behavior-change topics
Support	"Lifestyle coach" • emailed answers to questions • sent scheduled unsolicited emails offering support and feedback on participants' progress with the curriculum, self-monitoring, workbook entries, weight change*

Data Collection: Data were collected at baseline, 6-months and 12-months. Baseline data

included demographic information, as well as health status, use of medications to treat cardiovascular risk factors (CVRF) such as hypertension, diabetes or dyslipidemia, use of tobacco and alcohol, personal weight loss history, social support, prior computer use, functional health literacy, transportation and employment, and health care utilization. The primary outcome variable was weight change. Data needed to assess secondary outcomes were collected as shown in Table 2.

Limitations: The study design is limited by the lack of a true control group, necessitated by its goal of evaluating these interventions in the context of actual patient care. To engage providers in referring patients, and to be consistent with recommendations for practical trials, we felt that it was important to provide a true, policy-relevant intervention for all participants. Another limitation reflects the large number of software malfunctions that occurred during the trial. It is difficult to differentiate any effect of compromised intervention fidelity (due to malfunctioning software) from the trial outcomes.

Results

Principal findings:

On average, the sample was middle-aged, primarily white (20% African American) and non-Hispanic (Table 2). Most participants were married and well-educated. On average, blood pressure was well-controlled, and smoking was uncommon, but many patients reported weight-related health problems, especially high blood pressure (56%) and cholesterol problems (50%).

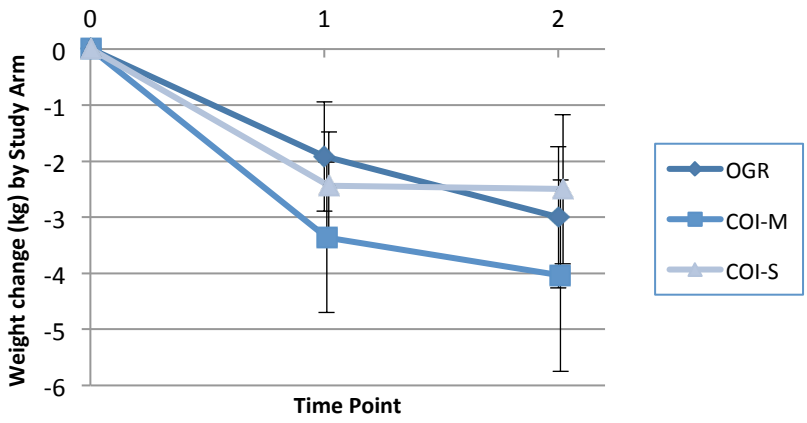
All study arms lost weight at 6 months, with the largest effect size seen in the COI-M group [-3.36, 95% confidence interval (CI) -4.70,-2.02], the smallest effect size seen in the OGR arm [-1.91 (CI: -2.89,-0.94)] and an intermediate point estimate seen for the COI-S arm [-2.44 (CI: -3.39,-1.48)]. Weight loss was sustained at 12 months in each study arm, with point estimates for weight declining in the COI-M and OGR arms over the second half of the intervention (Figure 1). At each time point, there was no

Table 2. Baseline sample description

	COI-M (n=129)	**COI-S (n=126)**	**OG_R (n=118)**
Age	49.57 ± 12.60	48.74 ± 13.31	49.89 ± 11.85
Gender			
Male	30 (23.3%)	31 (26.3%)	30 (23.8%)
Female	99 (76.7%)	87 (73.7%)	96 (76.2%)
Race			
White	96 (74.4%)	93 (78.8%)	99 (78.6%)
Black	30 (23.3%)	20 (17.0%)	26 (20.6%)
Asian	2 (1.6%)	4 (3.4%)	0 (0.0%)
Other	1 (0.8%)	0 (0.0%)	0 (0.0%)
Not Sure	0 (0.0%)	1 (0.9%)	1 (0.80%)
Ethnicity			
Not Hispanic/Latino	129 (100.0%)	118 (100.0%)	124 (98.4%)
Hispanic/Latino	0 (0.0%)	0 (0.0%)	2 (1.6%)
Marital Status			
Single	30 (23.8%)	24 (20.3%)	26 (20.8%)
Married	77 (61.1%)	83 (70.3%)	81 (64.8%)
Separated/Divorced	17 (13.5%)	7 (5.9%)	13 (10.4%)
Widowed	2 (1.6%)	4 (3.4%)	5 (4.0%)
Education			
HS/GED	16 (12.4%)	12 (10.2%)	16 (12.7%)
Some College	39 (30.2%)	26 (22.0%)	27 (21.4%)
Completed College	33 (25.6%)	43 (36.4%)	43 (34.1%)
Graduate Degree	41 (31.8%)	37 (31.4%)	40 (31.8%)
Weight (kg)	108.30 ± 19.88	105.93 ± 23.31	103.91 ± 18.25
SBP	128.67 ± 16.50	128.12 ± 14.42	128.70 ± 16.47
DBP	79.39 ± 11.25	79.37 ± 9.02	79.11 ± 8.88
Medical History			
Smoking	5 (4.0%)	8 (6.8%)	2 (1.6%)
Pre-diabetes	28 (21.7%)	17 (14.4%)	17 (13.5%)
Diabetes	26 (20.2%)	22 (18.6%)	26 (20.6%)
High blood pressure	77 (59.7%)	69 (58.5%)	63 (50.0%)
Cholesterol problems	73 (56.6%)	58 (49.2%)	57 (45.2%)
Sleep apnea	19 (14.7%)	31 (26.3%)	25 (19.8%)
GERD	29 (22.5%)	30 (25.4%)	23 (18.3%)
Arthritis in knees	34 (26.4%)	23 (19.5%)	23 (18.3%)
Heart failure/CHF	2 (1.6%)	1 (0.9%)	2 (1.6%)
Atherosclerotic disease	5 (3.9%)	3 (2.5%)	5 (4.0%)

significant difference in weight loss between groups.

Figure 1. *Weight change (95% CI) at baseline, 6 months and 12 months*



Systolic blood pressure increased slightly in the OGR and COI-M arms, and was stable in the COI-S arm at 6 months, and was unchanged from baseline values in all groups at 12 months. Physical functioning, as measured by the brief WOMAC instrument, worsened slightly and transiently in the OGR and COI-S arms and remained stable in the COI-M arm but at 12 months was unchanged from baseline values in all three groups. Point estimates for physical activity declined by about 1000 steps per day over the first 6 months and then increased slightly over the final six months of intervention. None of these secondary outcomes showed a significant difference across study arms.

Mean (95% CI) change in blood pressure, physical functioning and physical activity

Variable	OGR (n=118)	COI Mod (n=129)	COI Stan (n=126)	p-value
Baseline to 6 months				
SBP	5.09 (1.99, 8.18)	4.21 (1.26, 7.15)	2.75 (-0.60, 6.10)	0.5745
DBP	1.13 (-0.94, 3.21)	-0.40 (-2.54, 1.73)	0.87 (-1.20, 2.93)	0.5445
WOMAC Function	2.57 (0.05, 5.09)	-0.08 (-3.13, 2.97)	3.57 (1.26, 5.88)	0.1405
Total Steps	-1,034.5 (-1,449, -620)	-940.37 (-1,360, -521)	-1,086.4 (-1,544, -628)	0.8926
6 months to 12 months				
SBP	1.94 (-1.09, 4.98)	1.49 (-2.04, 5.02)	-0.44 (-3.61, 2.72)	0.5441
DBP	-0.56 (-2.67, 1.56)	-0.61 (-2.85, 1.63)	0.16 (-2.05, 2.37)	0.8588
WOMAC Function	2.83 (-0.21, 5.87)	0.62 (-2.20, 3.43)	2.34 (-0.36, 5.04)	0.5316
Total Steps	-564.53 (-1002, -127)	-664.43 (-1126, -203)	-713.78 (-1289, -139)	0.9073

The cost-effectiveness analysis was not completed at the time of this report. Staff changes delayed its initiation and a request to extend the timeline sufficiently to use unspent allocated funding to complete the analyses was denied.

Discussion

All three interventions led to weight loss over 1 year of follow-up, and weight regain was not seen in any group. The study was under-powered to detect the 1 kg difference in weight change that was found between the COI-M and OGR groups. The COI-M interventions 4.04 kg effect size is quite consistent with other successful online interventions[24] and is similar to the effect size we anticipated from our prior work.

It is unclear why the COI-S intervention led to only 2.50 kg of weight loss. One possibility is that technical malfunctions that the study experienced with the COI software disproportionately impacted the COI-S arm. For example, if COI-S participants had a tendency to log in more often than the COI-M participants in response to their more intensive (scheduled versus as-needed) coaching, they would have been more exposed to the technical concerns that arose. One likely response to software problems is

disengagement with the program. Another possibility is that the online tool to help coaches identify COI-M participants who were not meeting program goals may have negatively impacted the coaching of the COI-S participants, since the same coaches worked with participants in both study groups. For example, if the coaches came to rely on the coaching flags to identify areas in which participants' needed help, they may have been less likely to offer the most relevant coaching advice each week to COI-S versus COI-M participants.

The least intensive intervention (OGR) led to more weight loss (3.0 kg at 1 year) than expected from the literature. Multiple non-intensive primary-care based interventions have shown an effect size of less than 3 kg at one year of follow-up.[25-30] An IT focus could offer more promise for a minimal intervention in coordination with primary care than in-person programs have indicated. However, our survey data also indicate that more OGR participants used another approach to weight loss (besides their OCELOT-PC intervention) at 6 months of enrollment than did COI-M or COI-S participants (14.4%, 6.3%, and 3.4%, respectively). The relative success of the OGR arm may thus reflect cost and effort outside of the study intervention – with participants to whom we gave minimal assistance finding some other way to help themselves.

While we did not see a blood pressure effect in this study, it should be noted that the participants' blood pressure was generally well controlled at baseline (poorly controlled blood pressure was an exclusion criteria). Furthermore, as all patients had established primary care, we expect that any elevations in blood pressure may have been pharmacologically treated in addition to the OCELOT-PC lifestyle intervention. The fact that the sample was not selected according to physical functioning status may also explain, in part, why the interventions did not impact the participants' physical functioning score. It is unclear why the intervention did not impact physical activity.

Due to the encouraging findings from the COI-M arm, previously collected data indicating high levels of patient satisfaction with the intervention,[31] and a need to minimize technical malfunctions, the research team has worked with a new vendor to develop a new platform (largely funded by the University of Pittsburgh) to deliver the COI-M intervention as part of our efforts to disseminate any effective intervention from the study. We are hoping to be able to disseminate this intervention to primary care settings in an affordable, sustainable manner and with appropriate technical support.

Conclusions

- All three interventions led to weight loss over 1 year of follow-up
- Weight regain was not seen in any group
- The study was under-powered to detect the 1 kg difference in weight change between groups that was found

Significance and Implications

- Online lifestyle support can be implemented in coordination with primary care medicine.
- All of the interventions examined offer more intensive obesity intervention than is typical in the primary care setting.
- While we found no statistically significant difference in the effect size between the three groups, point estimates suggest that the more intensive intervention had a more clinically significant impact.
- An online counselor can extend the preventive counseling impact of the primary care health team to reach more patients – during their normal routines, when lifestyle decisions are made – than a counselor's whose advice is limited to face-to-face encounters.

Publications and Products

Scientific Publications: Several manuscripts for publication are underway.

Dissemination efforts:

Website to disseminate findings and resources such as the instructions for online lifestyle coaching using the comprehensive online lifestyle self-management support platform as well as a site from which to disseminate access to the online intervention in the future (www.ppit.pitt.edu)

Manual on delivering online lifestyle counseling *(Simkin-Silverman LR, Conroy MB, McTigue KM, General online lifestyle coaching tips, Copyright University of Pittsburgh 2012).* This document provides practical advice for lifestyle counselors who are aiming to adapt their counseling skills for the online setting, and will be posted to the dissemination website.

Software for delivering the comprehensive online intervention (primarily funded by the University of Pittsburgh)

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